K021937

10. 510 (k) Summary

OCT 11 2002

10.1. Common

10.1.1. Regulatory Code

Code of Federal Regulations Title 21, Volume 8: Revised as of April 1, 2001
21CFR886.1930

10.1.2. Company Name/Contact

Distributor in USA:
Ralf Thomaier
Truevision Instruments
4220 Cesar Chavez #536
San Francisco, CA94131
Tel: (415)-643 98 38
Fax: (415)-643 98 39

Manufacturer:
Ryazan State Instrument-Making Enterprise
32 Kalyaev St.
Ryazan, 390 000 Russia

10.1.3. Medical Specialty

Ophthalmic

10.1.4. Name of Device

Trade name:	Tonometer TGDc-01"PRA"
Common Name:	Tonometer and accessories subpart B - Diagnostic devices

10.1.5. Product Code

HKX

10.1.6. Device Class

Class II

10.1.7. Regulation Number

886.1930

10.1.8. Predicate Devices

The TGDc-01 "PRA" is substantially equivalent to the following legally marketed devices:

GOLDMAN MANUAL TONOMETER --- produced by GOLDEN VISION, INC. 7436 S.W. 117TH AVE.,SUITE 103 MIAMI, FL 33183 3816	510(k) Number: K981432
CANON NON-CONTACT TONOMETER T-2 --- produced by CANON, INC. 30-2 SHIMOMARUKO 3-CHOME OHTA-KU, TOKYO, JAPAN, JA 146	510(k) Number: K943939

10.2. Intended Use

Quick and accurate measurement of IOP in various situations independent of place and time is the dream of every ophthalmologist. Today the portable tonometer TGDc-01 "PRA" gives you that capability. This new IOP measuring method through the eyelid in the sclera area, unique to our device, eliminates completely any effect on the mucous eye membrane.

- Painless diagnostics without anesthetics and antiseptics
- Elimination of infection risk
- Measuring results independent of cornea's crookedness
- Evaluation of IOP in patients after any operations on cornea
- IOP measurement in children
- Monitoring of Glaucoma treatment

10.3. Technological Characteristics

Measurement range	5-60 mm Hg
The time of a single measurement, not more	3 sec.
Autonomous power supply: 2 feed elements CR2032 "VARTA" or similar. Supply voltage	3 V
Number of measurements using one set of feed elements, not less	1500
Serviceability, not less	8 years
Weight, not more	79 g
Dimensions, not more	173,5 õ 25,5 õ 19,5 mm

FEATURES	TGDc-01	Goldmann Tonometer	Shiotz Tonometer	Air-jet	Tono Pen
No direct effect on the cornea	+				
Portability	+		+		+
Displays independence from cornea's crookedness.	+		+	+	
Digital IOP indication	+	+		+	+
Measurement in sitting position	+	+		+	+
Measurement in supine position	+		+	+	+
Short-time measurement	+			+	+
Sterilization is not required	+			+	+
Anesthesia is not required	+			+	

10.4. Conclusion

The results of the comparison medical tests of Tonometer TGDc–01 "PRA" and Goldmann tonometer as well as Canon Tonometer T–2 demonstrated their **high coincidence degree** in the whole range with the compared devices. We achieved the same results from all devices.

Taking into account the comparison medical tests findings as well as tonometer TGDc–01 "PRA" advantages (anesthetics and antiseptics are not necessary; elimination of infection risk; short–time measurement; results independent of cornea's crookedness) its wide application in ophthalmology is recommended alongside with Goldmann tonometer and Canon tonometer, especially while carrying out **mass examination of population**. Also, it is **recommended for use at home** to control ophthalmotonus condition **under drugs and medical treatment**.

Tonometer TGDc–01 "PRA" represents **new technology** to ophthalmology. It is compact, handy, and can be easily **placed in a smock pocket or in a handbag**.

Portability, safety and simplicity make tonometer TGDc–01 "PRA" ideal for a **wide range of application**:

- for mass examination of the population
- at the patient's bedside

- in geriatrics homes
- in children hospitals
- at the army
- at home.

Tonometer TGDc–01 "PRA" is not only good for determining the potential for glaucoma onset. It can also be used for **monitoring treatement effectiveness throughout the day**. Unlike other Tonometers, TGDc–01 "PRA" can be used **repeatedly during the day with no effect on the eye.**

Tonometer TGDc–01 "PRA" is **easy to use**. A simple operating manual will be provided with each device. It takes only some seconds to measure the IOP, with the patient in a sitting or supine position. The IOP measurement is displayed on an LCD screen of the device. To test the tonometer's operational integrity there is a pressure control device provided.

Tonometer TGDc–01 "PRA" uses the latest technologies which provide it high reliability, quality and longevity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Truevision Instruments
c/o Mr. Ralf Thomaier
4220 Cesar Chavez #536
San Francisco, CA 94131

Re: K021937
Trade Name: Tonometer TGDc-01 "PRA"
Classification Regulation Number: 886.1930
Regulatory Class: II
Product Code: HKX
Dated: September 19, 2002
Received: September 23, 2002

Dear Mr. Thomaier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE FORM **FDA/CDRH/510K PROGRAM**

510(k) Number (if known): K021937

Device Name: TGDc-01 PRA TONOMETER

Indications For Use:

The TGDc-01 PRA Tonometer is used to measure intraocular pressure (IOP).
The device is intended for use in the diagnosis of glaucoma and for monitoring IOP.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Dennis L McCarthy
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K021937